

## Remarks

### I. Status of the Application and Claims

As originally filed, the present application had a total of 14 claims. These were cancelled in a Preliminary Amendment and claims 15-36 were added. All of these claims have been cancelled herein and new claims 37-56 have been introduced.

### II. The Amendments

The specification of the application has been amended to define the abbreviation "FDH." Claims 37-56 have been added and are fully supported by the application as originally filed. It is therefore respectfully requested that these amendments be entered.

### III. Comments Regarding Priority

On pages 2-3 of the Office Action, the Examiner suggests that claims are not entitled to the priority date of the international and earlier national stage applications because they require that no surfactant be present whereas the prior applications only required that no surfactant be added.

Although they are not in agreement with the Examiner, Applicants have amended claims so that they now recite no "added" surfactant. Thus, it is respectfully submitted that the Examiner's objection has been obviated.

### IV. Objection to the Specification

On page 2 of the Office Action, the Examiner objects to the specification based upon the allegation that the abbreviation "FDH" should have been defined the first time that "formate dehydrogenase" appears in the application. In response, Applicants have complied with the Examiner's suggestion. They therefore believe that the present objection has been overcome.

## The Rejections

### I. Rejection of Claims Under 35 U.S.C. § 101

On pages 3-4 of the Office Action, the Examiner argues that the present claims are directed to a "system" and that this is not a recognized class of invention. The Examiner suggests that claims be amended so they are directed to a process. In response, Applicants have complied with the Examiner's suggestion. It is therefore respectfully submitted that the present rejection has been overcome.

### II. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

On pages 4-6 of the Office Action, the Examiner makes several rejections under 35 USC § 112, second paragraph. Below, Applicants respond to each allegation.

A. The Examiner alleges that the relationship between the terms "organic compound" and "substrate" is unclear. In response, Applicants have amended claims to eliminate reference to a "substrate."

B. The Examiner argues that the term "higher than or equal to its solubility limit" is indefinite because a specific compound, temperature and solvent are not recited in the claims.

Applicants respectfully traverse this rejection.

There seems to be some confusion concerning the significance of the solubility limitation. It is present in claims because reactions must take place in a system in which the organic compound (the substrate in the reactions) is part of an emulsion or suspension. The solvent itself is purely aqueous and the emulsion is formed due to the presence of the organic compound. Obviously, this will not occur if the organic compound is present at a concentration lower than its solubility limit. Applicants also respectfully submit that one of ordinary skill in the chemical arts certainly understands the meaning of "solubility limit" and would have no difficulty in determining this for any given compound and set of conditions. It is therefore respectfully submitted that the term used by Applicants is not indefinite.

C. The Examiner rejects dependent claims having the terms "reaction mixture" or "desired product" because these terms allegedly lack proper antecedent basis. In response,

Applicants have amended independent claim 37 so that it now provides antecedent basis for the terms referred to by the Examiner.

D. On pages 5-6, the Examiner rejects claims for failing to recite sufficient steps to define a full chemical process. In response, Applicants have amended claim 37 so that a complete process is now provided. It is therefore respectfully submitted that the Examiner's basis for rejection has been overcome.

## **II. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

### **A. Written Description**

On pages 6-10 of the Office Action, claims are rejected based upon the written description requirement of 35 USC §112. This rejection appears to be based upon three arguments: a) the claims do not recite a full range of process steps and are therefore open ended; b) insufficient examples are provided to support the scope of the claims; and c) Federal Circuit decisions require that genes and proteins be defined structurally.

Applicants respectfully traverse this rejection.

With respect to the first argument, Applicants believe that the claims as amended now recite a full process.

With respect to the argument that insufficient examples are provided, Applicants have amended claims so that they are limited to aldehydes, ketones and alcohols. Several examples are given demonstrating the conversion of ketones and aldehydes in accordance with the invention (see Examples 3-7). The conversion of alcohols to aldehydes and ketones is simply the reverse of the reactions. These types of reactions are certainly very well known in the art and the Examples provided should be clear evidence that Applicants were in possession of the claimed invention at the time of filing. Moreover, Applicants are only claiming the reactions to the extent that they are carried out in purely aqueous solvents and in which an organic substrate is used at a high enough concentration to form an emulsion or a suspension. Thus, Applicants submit that the written description requirement of patentability has been met.

Finally, it is respectfully submitted that court decisions requiring that genes and proteins be defined structurally must be read in context. To Applicants knowledge, all of these cases were concerned with claims to a gene or protein per se and the rationale underlying the decisions was that a purely functional definition would not allow one of skill in the art to distinguish known and future genes or proteins from those claimed. This is clearly not relevant to the claims now pending. They are directed to a chemical process not a gene or protein per se. Moreover, they are concerned with reaction conditions that should either be clearly present or not present in any other given process. Thus, Applicants respectfully submit that the written description requirement of patentability has been met.

#### **B. Enablement**

On pages 6-12 of the Office Action, claims are rejected based upon the enablement requirement of patentability. The Examiner argues that, although the claims are enabled with respect to aldehydes and ketones, there is insufficient support for other compounds.

In response, Applicants submit that claims are now limited to the reduction of aldehydes and ketones to alcohols and to the reverse reaction, *i.e.*, the oxidation of alcohols to aldehydes and ketones. In light of the Examples provided, Applicants submit that the amended claims meet the enablement requirement of patentability.

#### **II. Rejection of Claims Under 35 U.S.C. § 103**

On pages 12-15 of the Office Action, claims are rejected as being obvious in light of Bomannus (US 2003/0054520), Yamamto ( US 2002/0064847) or Sjoberg (US 6,500,661). In each case, the Examiner alleges that the reference teaches a coupled reaction involving the oxidation or reduction of a substrate and the use of NAD(P)/NAD(P)H as a cofactor. The Examiner does not point to specific parts of the references suggesting the elements required by Applicants' claims and simply alleges that any differences that may exist are either obvious or represent a difference of little significance, *e.g.*, a mere optimization of standard reaction parameters.

Applicants respectfully traverse this rejection.

Applicants have never contended that reductions and oxidations using coupled enzymatic reactions and NAD(P)/NAD(P)H as a cofactor were not known in the art. In fact, prior work in this area is disclosed on pages 1-4 of the application. As discussed therein, a problem with these reactions occurs in situations where the substrate is poorly soluble in the aqueous medium used for enzymes. Attempts to solve this problem have involved increasing the solubility of the substrate by adding a polar organic solvent or surfactant to systems and carrying out reactions in a two phase system. In contrast, Applicants use a purely aqueous solvent and a substrate that is at a concentration above its solubility limit (resulting in the presence of an emulsion or suspension). The advantage of this is that, at a high concentration of substrate, enzymes maintain high activity in the purely aqueous system whereas activity is lost in the presence of organic solvents (see Example 1).

None of the references cited by the Examiner describes a reaction that takes place under the conditions required by Applicants' claims, *i.e.*, in which an organic substrate is used in a purely aqueous solvent system at a concentration above its solubility limit. There is no suggestion to perform reactions in an emulsion or suspension or even a recognition of a need to adapt reaction systems to maintain good results when an organic substrate is employed. The performing of reactions in an emulsion or suspension and at concentrations where the substrate is insoluble clearly goes beyond a mere optimization of standard reaction parameters. Unless the Examiner can specifically point to something in one or more of the cited references that suggests the reaction conditions required by the pending claims, Applicants submit that a *prima facie* case of obviousness cannot be validly maintained.

### Conclusion

In light of the considerations above, Applicants respectfully submit that all of the Examiner's rejections have been overcome. It is therefore requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (240)683-6165.

Respectfully submitted,  
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